

|  |  |   |
|--|--|---|
| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>22D2078062                             | <b>(X3) Date Survey Completed</b><br><br>09/06/2018 |
| <b>Name of Provider or Supplier</b><br><br>Urology Group Of Western New England Pc   | <b>Street Address, City, State</b><br><br>115 West Silver Street, Noble Hospital 1st Fl, Westfield, MA |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |  |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>   |
|---------------------------|--|
| <b>D0000</b>              | An initial CLIA certification survey was conducted for the Urology Group of Western New England laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. .   |
| <b>D5423</b>              | <p><b>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE</b><br/>CFR(s): 493.1253(b)(2)</p> <p>Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on record review and interview, the laboratory failed to perform validation studies to validate all aspects of test performance prior to implementing the urine colony count screening procedure for patient testing and reporting as evidenced by the following: Urine colony count: a) The "List of Laboratory Test Performed On-Site" form indicated that in January of 2018 the laboratory put into place urine culture screens (urine colony counts on bi plate media). b) A review of the validation study for the procedure revealed that the validation of ten (10) patient urine specimens was performed in June of 2018 and signed off by the technical consultant on 7/2/18. c)</p> |

Interview with the technical consultant on 9/6/18 at 9:35 AM confirmed that the laboratory failed to perform validation studies prior to implementing the test for patient sample testing and reporting.